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ARTICLE 5. SEALED SOURCE INDUSTRIAL RADIOGRAPHY

R12-1-541. Enclosed Radiography Using X-ray Machines

- A. Certified and certifiable cabinet x-ray systems, as defined in Article 1, are exempt from the requirements of Article 5, provided the following conditions are met:
 - 1. The registrant shall make, or cause to be made, an evaluation of each certified and certifiable cabinet x-ray system, at intervals not to exceed 12 months, to determine conformance with the standards for certified and certifiable cabinet x-ray systems defined in Article 1. Records of the evaluations shall be retained for three years from the date of their creation; and
 - 2. Physical radiation surveys shall be performed with a survey instrument appropriate for the energy range and levels of radiation to be assessed and calibrated within the preceding 12 months.
- B. The registrant shall ensure that cabinet x-ray systems not exempted in subsection (A) comply with the recordkeeping requirements of this Article and the following special requirements:
 - 1. Radiation levels measured at 5 centimeters (2 inches) from any accessible exterior surface of the enclosure shall not exceed 50 microsievert (0.5 milliroentgen) in one hour for any combination of technical factors (i.e., mA, kVp);
 - 2. Access to the interior of the enclosure shall be possible only through interlocked

- doors or panels that allow production of radiation only when all interlocked doors or panels are securely closed. Opening any point of access shall result in immediate termination of radiation production, and subsequent reactivation of the x-ray tube shall only be possible at the control panel;
- Visible warning signals that are activated only during production of radiation shall be provided at the control panel and at each point of access to the interior of the enclosure;
- 4. The registrant shall make, or cause to be made, evaluations of each x-ray system to determine conformance with this Article, before placing the x-ray system into use and thereafter at intervals not to exceed three months. Records of the evaluations shall be retained for two years, and
- 5. Physical radiation surveys to satisfy the requirements of subsection (B)(4) shall be performed only with instrumentation meeting the requirements of R12-1-504.
- C. The registrant shall ensure that shielded room x-ray systems comply with the recordkeeping requirements of this Article and the following special requirements;
 - 1. Each x-ray room shall be so shielded that every location on the exterior meets the requirements for an "unrestricted area" as specified in R12-1-416;
 - 2. Access to the interior of a shielded x-ray room shall only be possible through doors or panels which are interlocked. Radiation production shall be possible only when all interlocked doors and panels are securely closed. Opening of any interlocked access points shall result in immediate termination of radiation production, and subsequent reactivation of the x-ray tube shall only be possible at the control panel;
 - 3. Each access point shall be provided with two interlocks, each on a separate circuit

- so that failure of one interlock will not affect the performance of the other;
- 4. Visible warning signals activated only during production of radiation shall be provided at the control panel and at each point of access into the shielded room;
- 5. The registrant shall make, or cause to be made, evaluations of each shielded room x-ray system before placing the system into use and thereafter at intervals not to exceed three months to determine compliance with this Article. Records of the evaluations shall be retained for two years.
- 6. Radiation surveys performed to determine exposure shall be performed with instrumentation that meets the requirements of R12-1-504;
- 7. Electrical interlocks and warning devices shall be inspected for proper operation at the beginning of each period of use, and records of the inspections shall be prepared and retained for two years;
- 8. The registrant shall not permit any individual to operate an x-ray machine for shielded room radiography unless that individual has received a copy of, and instruction in, the operating procedures and has demonstrated competence in the safe use of the equipment;
- 9. An individual shall not occupy the interior of any shielded room x-ray system during production of radiation; and
- 10. The registrant shall provide personnel monitoring devices that meet the requirements of R12-1-523(C) to each shielded room x-ray machine operator, and require that each operator use the devices.
- 11. The registrant shall maintain records of:
 - a. Quarterly inventories for mobile systems, as prescribed in R12-1-506; and
 b. Utilization of all systems, as prescribed in R12-1-507.

- 12. Records shall be maintained for three years from the date of the inventory or utilization.
- D. The registrant shall connect an enclosed radiography machine to the electrical system in a manner that will prevent a ground fault from generating x-radiation.

R12-1-542. Baggage Inspection Systems

- A. For x-ray systems designed to screen carry-on baggage at airlines, railroads, bus terminals, or similar facilities, a registrant shall station the operator at the control area in a position that permits surveillance of the ports and doors during generation of x-radiation to prevent exposure to passengers and other members of the public.
- B. For an exposure or preset succession of exposures of one-half second or greater duration, a registrant shall use a system that enables the operator to terminate the exposure or preset succession of exposures at any time.
- C. For an exposure or preset succession of exposures of less than one-half second duration, a registrant shall use a system that allows the operator to complete the exposure in progress, but prevent additional exposures.
- **D.** A registrant shall operate a baggage inspection system according to the manufacturer's instructions.
- E. A registrant shall not disconnect or otherwise tamper with the safety systems of a baggage inspection system, except for maintenance purposes.
- F. In addition to the requirements in this Section, registrants using a baggage inspection system shall meet the requirements in R12-1-541(A), (B), and (D).

ARTICLE 11 INDUSTRIAL USES OF X-RAY, NOT INCLUDING ANALYTICAL SYSTEMS

R12-1-1102 Definitions

"Access panel" means any panel that is designed to be removed or opened for maintenance or service purposes, opened using tools, and used to provide access to the interior of the cabinet x-ray unit.

"Annual refresher safety training" means a review conducted or provided by the registrant for its employees on radiation safety aspects of industrial radiography. The review shall include, as applicable, the results of internal inspections, new procedures or equipment, new or revised state rules, accidents or errors that have occurred, and provide opportunities for employees to ask safety questions.

"Aperture" means any opening in the outside surface of the cabinet x-ray unit, other than a port, which remains open during generation of x-radiation.

"Door" means any barrier that is designed to be movable or opened for routine operation purposes, not opened using tools, and used to provide access to the interior of the cabinet x-ray unit.

"Ground fault" means an accidental electrical grounding of an electrical conductor.

"Hands-on experience" means accumulation of knowledge or skill in any area relevant to radiography.

"Port" means any opening in the outside surface of the cabinet x-ray unit that is designed to remain open, during generation of x-rays, for conveying material being irradiated into and out of the cabinet, or for partial insertion of an object for irradiation whose dimensions do not permit

complete insertion into the cabinet x-ray unit.

"Practical examination" means a demonstration, through practical application of safety rules and principles of industrial radiography, including use of all radiography equipment and knowledge of radiography procedures.

"Radiographic operations" means all activities associated with use of a radiographic x-ray system. This includes performing surveys to confirm the adequacy of boundaries, setting up equipment, and conducting any activity inside restricted area boundaries.

R12-1-501. Definitions

R12-1-1140 Enclosed Radiography

- A. The Agency has determined that certified and certifiable cabinet x-ray systems, as defined in Article 1, are exempt from the requirements of Article 5, provided the following conditions are met:
 - 1. The registrant shall make, or cause to be made, an evaluation of each certified and certifiable cabinet x-ray system, at intervals not to exceed 12 months, to determine conformance with the standards for certified and certifiable cabinet x-ray systems defined in Article 1. Records of the evaluations shall be retained for three years from the date of their creation; and
 - 2. The registrant performs a physical radiation survey with a survey instrument appropriate for the energy range and levels of radiation to be assessed and calibrated within the preceding 12 months.
- A registrant shall ensure that cabinet x-ray systems not exempted in subsection (A) comply with the record keeping requirements of this Article and the following special requirements:

- 1. Radiation levels measured at 5 centimeters (2 inches) from any accessible exterior surface of the enclosure shall not exceed 50 microsievert (0.5 milliroentgen) in one hour for any combination of technical factors (i.e., mA, kVp);
- 2. Access to the interior of the enclosure shall be possible only through interlocked doors or panels that allow production of radiation only when all interlocked doors or panels are securely closed. Opening any point of access shall result in immediate termination of radiation production, and subsequent reactivation of the x-ray tube shall only be possible at the control panel;
- <u>Visible warning signals that are activated only during production of radiation shall</u>
 <u>be provided at the control panel and at each point of access to the interior of the enclosure;</u>
- 4. The registrant shall make, or cause to be made, evaluations of each x-ray system to determine conformance with this Article, before placing the x-ray system into use and thereafter at intervals not to exceed three months. Records of the evaluations shall be retained for two years, and
- 5. The registrant performs a physical radiation survey to satisfy the requirements of subsection (B)(4) shall be performed only with instrumentation meeting the requirements of R12-1-1108.
- C. A registrant shall ensure that shielded room x-ray systems comply with the record keeping requirements of this Article and the following special requirements;
 - Each x-ray room shall be so shielded that every location on the exterior meets the requirements for an "unrestricted area" as specified in R12-1-416;
 - 2. Access to the interior of a shielded x-ray room shall only be possible through doors or panels which are interlocked. Radiation production shall be possible only when

- all interlocked doors and panels are securely closed. Opening of any interlocked access points shall result in immediate termination of radiation production, and subsequent reactivation of the x-ray tube shall only be possible at the control panel;
- 3. Each access point shall be provided with two interlocks, each on a separate circuit so that failure of one interlock will not affect the performance of the other;
- 4. <u>Visible warning signals activated only during production of radiation shall be</u>
 provided at the control panel and at each point of access into the shielded room;
- 5. The registrant shall make, or cause to be made, evaluations of each shielded room x-ray system before placing the system into use and thereafter at intervals not to exceed three months to determine compliance with this Article. Records of the evaluations shall be retained for two years.
- 6. Radiation surveys performed to determine exposure shall be performed with instrumentation that meets the requirements of R12-1-1108;
- 7. Electrical interlocks and warning devices shall be inspected for proper operation at the beginning of each period of use, and records of the inspections shall be prepared and retained for two years;
- 8. The registrant shall not permit any individual to operate an x-ray machine for shielded room radiography unless that individual has received a copy of, and instruction in, the operating procedures and has demonstrated competence in the safe use of the equipment;
- An individual shall not occupy the interior of any shielded room x-ray system
 during production of radiation; and
- 10. The registrant shall provide personnel monitoring devices that meet the

- require that each operator use the devices.
- 11. The registrant shall maintain records of:
 - a. Quarterly inventories for mobile systems, as prescribed in R12-1-1110; and
 - <u>b.</u> <u>Utilization of all systems, as prescribed in R12-1-1112.</u>
- 12. The registrant shall maintain the records for three years from the date of the inventory or utilization.
- <u>A registrant shall connect an enclosed radiography machine to the electrical system in a manner that will prevent a ground fault from generating x-radiation.</u>

R12-1-1142. Baggage Inspection Systems

- A. For x-ray systems designed to screen carry-on baggage at airlines, railroads, bus terminals, or similar facilities, a registrant shall station the operator at the control area in a position that permits surveillance of the ports and doors during generation of x-radiation to prevent exposure to passengers and other members of the public.
- B. For an exposure or preset succession of exposures of ½ second or greater duration, a registrant shall use a system that enables the operator to terminate the exposure or preset succession of exposures at any time.
- <u>C.</u> For an exposure or preset succession of exposures of less than ½ second duration, a registrant shall use a system that allows the operator to complete the exposure in progress, but prevent additional exposures.
- <u>A registrant shall operate a baggage inspection system according to the manufacturer's instructions.</u>
- **E.** A registrant shall not disconnect or otherwise tamper with the safety systems of a baggage

inspection system, except for maintenance purposes.

<u>F.</u> In addition to the requirements in this Section, a registrant using a baggage inspection system shall meet the requirements in R12-1-1140(A), (B) and (D).

ARTICLE 13. LICENSE AND REGISTRATION FEES

R12-1-1302. License and Registration Categories

- **A.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
- **B.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - 6. No change
- C. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change

- 5. No change
- 6. No change
- 7. No change
- 8. No change
- 9. No change
- 10. No change
- 11. No change
- 12. No change
- 13. No change
- 14. No change
- 15. No change
- 16. No change
- 17. No change

D. No change

- 1. No change
 - a. No change
 - b. No change
- 2. No change
- 3. No change
- 4. No change
- 5. No change
- 6. No change
- 7. No change
- 8. No change

- 9. No change
- 10. No change
- 11. No change
- 12. No change
- 13. No change
- 14. No change
- 15. No change
- 16. No change
- 17. No change
- 18. No change
- 19. No change

E. No change

- 1. No change
- 2. No change
- 3. No change
- 4. No change
- 5. No change
- 6.. No change.

F. No change

- 1. No change
- 2. No change
- 3. No change
- 4. No change
- 5. A laser light show registration authorizes the operation of a laser device subject to

R12-1-1440 R12-1-1441.

- 6. A medical laser registration authorizes the operation of one or more laser devices subject to R12-1-1439 R12-1-1440.
- 7. A Class II surgical device registration authorizes the operation of one or more Class II surgical devices subject to R12-1-1417 R12-1-1438.
- 8. No change
- 9. No change
- 10. No change
- 11. No change
- 12. No change

ARTICLE 14. REGISTRATION OF NONIONIZING RADIATION SOURCES AND STANDARDS FOR PROTECTION AGAINST NONIONIZING RADIATION

R12-1-1402. Definitions

General definitions:

"Cosmetic procedure" means: Use of medical lasers or intense pulse light (IPL) devices, approved by the Federal Food and Drug Administration (FDA), for the purpose of spider vein removal, skin rejuvenation, non-ablative skin resurfacing, skin resurfacing, port wine stain removal, epidermal pigmented skin lesion, or tattoo removal.

"Direct supervision" means supervising the use of a radiation source for medical purposes by a licensed practitioner while present inside the facility where the radiation source is being used. "Indirect supervision" means: For lasers or IPL used for cosmetic procedures: there shall be, as a

minimum, responsible supervision and control by a licensed practitioner who is easily accessible by telecommunication. The supervising practitioner shall have ordered the application of radiation prior to its application, shall have established a method for emergency medical care in the absence of the supervising practitioner, and shall assume legal liability for the service rendered by the indirectly supervised operator, who has participated in sufficient supervised training, as specified in R12-1-1438, to allow the supervised operator to function under indirect supervision.

"Licensed practitioner" No change

"Medical Director" No change

"Nonexempt nonionizing radiation source" No change

Radiofrequency and microwave radiation:

"Accessible emission level" No change

"Far field region" No change

"Near field region" No change

"Radio frequency controlled area" No change

"Radio frequency exposure limits" No change

"Radio frequency source" No change

"Radio frequency radiation" No change

"Safety device" No change

Laser:

"Accessible emission level (AEL)" No change

"Accessible radiation" No change

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"Angular subtense" No change

"Aperture" No change

"Aperture stop" No change.

"Certified laser product" No change

"CDRH" No change

"Class 1 laser" No change

"Class 2 Laser" No change

"Class 2a laser products" No change

"Class 3a laser" No change

"Class 3b laser" No change

"Class 4 laser" No change

"Class 1, 2, 3, 4 facility" No change

"Collateral radiation" No change

"Continuous wave" (cw) No change

"Controlled area" No change

"Cosmetic procedure protocols" means delegated written authorization to select specific laser/IPL settings, initiate laser/IPL procedure, and exercise appropriate follow-up.

"Demonstration laser" No change

"Embedded laser" No change

"Enclosed laser" No change

"Federal performance standard for light-emitting products" No change

"Human access" No change

"Incident" No change

"Integrated radiance" No change

"Irradiance" No change

"Laser" No change

"Laser controlled area" No change

"Laser energy source" No change

"Laser product" No change

"Laser protective device" No change

"Laser radiation" No change

"Laser Safety Officer" No change

"Laser system" No change

"Limited Exposure Duration (T_{max})" No change

"Maintenance" No change

"Maximum permissible exposure (MPE)" No change

"Maintenance" No change.

"Operation" No change

"Protective housing" No change

"Pulse duration" No change

"Pulse interval" No change

"Radiance" No change

"Radiant energy" No change

"Radiant exposure" No change

"Radiant power" No change

"Safety interlock" No change

"Sampling interval". No change

"Secured enclosure" No change

"Service" No change

"T_{max}" No change

"Uncertified laser product" No change

Ultraviolet, high intensity light, and intense pulsed light source:

"Consumer" No change

"EPA" No change

"FDA" No change.

"High intensity mercury vapor discharge (HID) lamp" No change

"Intense pulsed light device" (IPL) means, for purposes of R12-1-1438, any lamp-based device

that produces an incoherent filtered intense light.

"Maximum exposure time" No change

"Protective sunlamp eye wear" No change

"Sanitize" No change

"Self-extinguishing lamp" No change

"Sunlamp product" No change

"Tanning device" No change

"Timer" No change

"Ultraviolet lamp" No change

"Ultraviolet radiation" No change

R12-1-1421. Laser Safety

A. No change

- **B.** No change
- **C.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change.
- **D.** A registrant The licensee shall retain records of:
 - Surveys Results of all physical surveys made to determine compliance with this
 Article;
 - Operating Records indicating any restriction in operating procedures necessary to prevent unnecessary or excessive exposure to laser or collateral radiation;
 - 3. <u>Incidents</u> Records relating to any incident for which reporting to the Agency is required in pursuant to R12-1-1436;
 - 4. <u>Medical Results of medical</u> surveillance to determine extent of injury resulting from exposure to laser or collateral radiation;
 - 5. No change
- **E.** The Laser Safety Officer shall meet the training requirements in Appendix D.

R12-1-1438. Hair Removal and Cosmetic Procedures Using Laser and Intense Pulsed Light

A. Hair Removal Procedures

When submitting an application for registration to use a medical laser or an IPL
 device for hair removal procedures that is a Class II or III surgical device certified

as complying with the design, labeling, and manufacturing standards in 21

CFR878.48 2003 edition, Published April 1, 2003, by the Office of Federal

Register National Archives and Records Administration, incorporated by reference and on file with the Agency, and containing no future editions or amendments, the applicant shall provide the following information with the application to the Agency for approval:

- a. Documentation demonstrating the licensed practitioner is qualified in accordance with this rule; and
- <u>b.</u> Documentation endorsed by a licensed practitioner, acknowledging
 responsibility for the minimum level of supervision of hair removal
 procedures, as defined in A.A.C. R12-1-1402 under "indirect supervision".
- When using a medical laser or an IPL device, that is a Class II or III surgical device certified as complying with the design, labeling, and manufacturing standards of the FDA, for hair removal procedures, A registrant shall.
 - a. Ensure the device is only used by a licensed practitioner, or by an operator under direct supervision of a licensed practitioner, or at a minimum, indirect supervision of the licensed practitioner.
 - Ensure that a Class II or III surgical device that will be used for hair
 removal procedures is purchased by or on the order of the licensed
 practitioner.
- 3. A registrant shall:
 - a. Not permit an unlicensed practitioner to use a medical laser or IPL system

for hair removal procedures until the individual:

- I. Has completed an approved medical laser assistant didactic training course of at least 40 hours in duration. Successful completion of the training program shall be based on a test consisting of a least 50 multiple choice questions on subjects covered, with a minimum grade of 80%. The training shall be provided by an individual who is eligible, through training and experience, to apply for laser safety officer certification or is a certified laser safety officer; and
- ii. Has completed a minimum of 24 hours of observation conducted under the direct supervision of a licensed practitioner;
- Has experience in at least 10 hair removal procedures performed by
 the registrant. The hands-on experience shall be conducted under
 the direct supervision of a licensed practitioner;
- Ensure that user follows written procedure protocols established by a licensed practitioner; and
- Ensure the user follows a written order provided by a licensed practitioner
 describing the specific site of hair removal.
- 4. A registrant shall maintain a record demonstrating that hair removal procedure protocols are approved by a licensed practitioner, and are reviewed by a licensed practitioner at least annually.
- 5. A registrant shall ensure that:
 - a. Procedure protocols are maintained on site, and that the protocols contain instructions to be given to the patient concerning follow-up monitoring;
 and

- b. Procedure protocols are designed to promote the exercise of professional judgement by the nurse or assistant commensurate with their education,
 experience and training; and need not describe the exact steps that a qualified assistant take with respect to the hair removal procedures.
- 6. A registrant shall ensure that a licensed practitioner observes the performance of each assistant operator during actual procedures at intervals not to exceed six months. A record of the observation shall be maintained for three years.
- 7. A registrant shall ensure the licensed practitioner is qualified to do hair removal procedures, by virtue of providing evidence to the registrant that the licensed practitioner has received appropriate training in physics, safety, surgical techniques, pre and post operative care, and can perform these procedures within the scope of practice as defined by the practitioner's licensing board.
- 8. The registrant shall ensure that radiation safety training is provided to all personnel involved with hair removal procedures, and shall ensure the training is commensurate with their involvement in the procedures. Records of training shall be available for Agency review for three years following assistant operator's period of employment.

B. Cosmetic Procedures

- 1. When using a medical laser or an IPL device, that is a Class II or III surgical device certified as complying with the design, labeling, and manufacturing standards of the FDA, for cosmetic procedures, A registrant shall.
 - a. Ensure the device is only used by a licensed practitioner, or by an operator
 under direct supervision of a licensed practitioner;
 - b. Ensure that a Class II or III surgical device, used for cosmetic procedures,

- is purchased by or on the order of the licensed practitioner.
- 2. A registrant shall not permit an unlicensed practitioner to use a medical laser or IPL system for cosmetic procedures until the individual has:
 - a. Completed an approved medical laser assistant didactic training course of at least 40 hours in duration. Successful completion of the training program will be based on a test consisting of a least 50 multiple choice questions on subjects covered, with a minimum grade of 80%. The training should be provided by an individual who is eligible, through training and experience, to apply for laser safety officer certification or is a certified laser safety officer;
 - b. Completed a minimum of 24 hours of observation, conducted under the direct supervision of a licensed practitioner; and
 - c. Completed hands on experience of at least 10 cosmetic procedures, for each type of procedure (spider vein removal, skin rejuvenation, non-ablative skin resurfacing, etc.). The hands-on experience shall be conducted under the direct supervision of a licensed practitioner.
- A registrant shall ensure that cosmetic procedure protocols are approved by the
 licensed practitioner in writing, and reviewed at least annually. Protocols shall be:
 - <u>Maintained on site</u>, and shall contain instructions to be given to the patient
 <u>for follow-up monitoring</u>; and
 - <u>b.</u> Designed to promote the exercise of professional judgment by the nurse or
 assistant commensurate with their education, experience and training; and
 need not describe the exact steps that a qualified assistant take with respect
 to cosmetic procedures .

- 4. A registrant shall ensure the licensed practitioner is qualified to do laser, IPL and related procedures, by virtue of providing evidence to the registrant that the licensed practitioner has received appropriate training in physics, safety, surgical techniques, pre and post operative care and can perform these procedures within the scope of practice as defined by the director's licensing board.
- 5. The registrant shall ensure that radiation safety training is provided to all personnel involved with cosmetic procedures, and shall ensure the training is commensurate with their involvement in the procedures. Records of training shall be available for Agency review for three years following assistant operator's period of employment.

R12-1-1439. Additional Requirements for Medical Laser Applications Laser/IPL User Safety Training

- A. Each Class III and Class IV medical laser product shall incorporate the means for measurement of the level of laser radiation intended for human irradiation, with an error in measurement of no greater than +/- 20%, when calibrated in accordance with the laser product manufacturer's calibration procedure.
- **B.** Medical lasers used for human irradiation shall be calibrated in accordance with the manufacturer's specified calibration procedure, at intervals not to exceed those specified by the manufacturer.
- C. The licensee shall ensure that medical lasers shall not be used for human irradiation unless all applicable requirements of this Article are met.
- D. In institutions where a number of different practitioners may use Class IIIb and Class IV lasers, a laser safety committee shall be formed to govern laser activity, establish use

- criteria, and approve operating procedures.
- 1. Membership on the committee shall include at least a representative of the Nursing staff,
 the Laser Safety Officer, a representative of institution management, and a
 representative of each medical discipline that utilizes the lasers.
- 2. The committee shall review actions by the Laser Safety Officer in hazard evaluation and the monitoring and control of laser hazards.
- 3. Users, and those ancillary personnel who may operate or assist in the operation of the lasers under the direction of the users, shall be approved by the committee.
 - E. For Class IIIb and IV lasers, the switch which controls patient exposure shall have a guard mechanism to prevent inadvertent exposure.
 - A person or organization seeking to initiate a medical laser/IPL operator training program, shall submit to the Agency for approval an application containing a description of the training program. The application shall include a course syllabus, including a test consisting of at least 50 multiple choice questions on subjects covered. The course material shall address all of the safety issues in R12-1-1421 through R12-1444, and Appendix C.
 - B. The Agency shall review the application in subsection (A) in a timely manner as required in A.A.C. R-12-2-301.
 - C. The Agency shall maintain a list of approved laser/IPL training programs.

Appendix C

Hair Removal and Cosmetic Laser/IPL Operator Training Program

General Considerations:

- 1. Training programs shall be specific to the medical laser/IPL system in use, and to the clinical procedures to be performed.
- Program criteria and content shall be in accordance with the facility policy and procedure,
 applicable standards, federal and state regulations.
- 3. The degree and type of training shall be appropriate for the hazards associated with the laser or IPL's in use.

Technical Considerations

- 1. Description of lasers and IPL's
- <u>2.</u> <u>Definitions</u>
- 3. <u>Laser/IPL radiation fundamentals</u>
- 4. Laser mediums and types of lasers solid, liquid, diodes, and gas and IPL's
- <u>5.</u> <u>Biological effects of laser/IPL light</u>
- 6. Damage mechanisms
 - <u>a.</u> Eye hazard
 - b. Skin hazard (skin type and skin anatomy)
 - c. Absorption wavelength effects
 - d. Thermal effects
- 7. Photo chemistry
- 8. <u>Criteria for setting Maximum Permissible Exposure (MPE) levels for eye and skin</u>
 Associated hazards
- <u>9.</u> Explosive, electrical, and chemical hazards
- 10. Photosensitive medications
- 11. Fire, ionizing radiation, cryogenic hazards, and others as applicable

Medical Considerations

- 1. Local anesthesia techniques, including ice, **EMLA@ cream** and other applicable topical treatments
- 2. Typical laser settings for hair removal and other cosmetic procedures
- 3. Expected patient response to treatments
- <u>4.</u> <u>Potential adverse reactions with treatment</u>
- 5. Anatomy and physiology of the skin areas to be treated
- 6. Indications and contraindications to use the pigment and vascular specific lasers for cutaneous procedures

General Laser/IPL safety

- 1. Laser/IPL classifications
- <u>2.</u> <u>Control measures including protective equipment</u>
- 3. Management and user responsibilities
- <u>4.</u> <u>Medical surveillance practices</u>
- 5. Federal and state regulatory requirements
- <u>6.</u> Related safety issues
 - <u>a.</u> Controlled access
 - <u>b.</u> <u>Plume management</u>
 - <u>c.</u> Equipment testing, aligning, and troubleshooting

Appendix D

Non Medical Laser User and Laser Safety Officer Training

- 1. For user personnel routinely working with or around lasers:
 - <u>a.</u> Fundamentals of laser operation (physical principals, construction, etc.)
 - b. Bioeffects of laser radiation on the eye and skin
 - <u>c.</u> <u>Significance of specular and diffuse reflections</u>
 - d. Non-beam hazards of lasers (electrical, chemical, reaction byproducts etc.)
 - e. <u>Ionizing radiation hazards (x-rays from power sources and target interactions when applicable)</u>
 - <u>f.</u> <u>Laser and laser system classifications</u>
 - g. Control measures
 - <u>h.</u> Overall responsibilities of management and employee
 - I. Medical surveillance practices (if applicable)
 - j. CPR for personnel servicing or working on lasers, with exposed high voltages and/or the capability of producing potentially lethal electrical currents
- 2. For the LSO or other individual responsible for the laser safety program, evaluation of hazards, and implementation of control measures, or any others if directed by management to obtain a thorough knowledge of laser safety:
 - a. The topics in 1. Above
 - b. Laser terminology
 - <u>c.</u> <u>Types of lasers, wavelengths, pulse shapes, modes, power/energy</u>
 - d. Basic radiometric units and measurements devices

- <u>e.</u> <u>MPE levels for eye and skin under all conditions</u>
- <u>f.</u> <u>Laser hazard evaluations, range equations, and other calculations</u>

3. Technical Considerations

- <u>a.</u> <u>Description of lasers and IPL's</u>
- <u>b.</u> <u>Definitions</u>
- <u>c.</u> <u>Laser/IPL radiation fundamentals</u>
- <u>d.</u> <u>Laser mediums and types of lasers solid, liquid, diodes, and gas and IPL's</u>
- e. Biological effects of laser/IPL light
- <u>f.</u> <u>Damage mechanisms</u>
 - (1). Eye hazard
 - (2). Skin hazard (skin type and skin anatomy)
 - (3). Absorption wavelength effects
 - (4). Thermal effects
- g. Photo chemistry
- <u>h.</u> <u>Photosensitive medications</u>
 - I. Criteria for setting Maximum Permissible Exposure (MPE) levels for eye

and skin

associated hazards

- <u>j.</u> <u>Explosive, electrical, and chemical hazards</u>
- <u>k.</u> <u>Photosensitive medications</u>
- <u>1.</u> Fire, ionizing radiation, cryogenic hazards, and others as applicable